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Patient Safety in Ambulatory Settings

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

This EPC evidence report is a Technical Brief. A Technical Brief is a rapid report, typically on an emerging medical technology, strategy or intervention. It provides an overview of key issues related to the intervention—for example, current indications, relevant patient populations and subgroups of interest, outcomes measured, and contextual factors that may affect decisions regarding the intervention. Although Technical Briefs generally focus on interventions for which there are limited published data and too few completed protocol-driven studies to support definitive conclusions, the decision to request a Technical Brief is not solely based on the availability of clinical studies. The goals of the Technical Brief are to provide an early objective description of the state of the science, a potential framework for assessing the applications and implications of the intervention, a summary of ongoing research, and information on future research needs. In particular, through the Technical Brief, AHRQ hopes to gain insight on the appropriate conceptual framework and critical issues that will inform future research.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

If you have comments on this Technical Brief, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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[To be added for the final report]

Key Informants

In designing the study questions, the EPC consulted a panel of Key Informants who represent subject experts and end-users of research. Key Informant input can inform key issues related to the topic of the technical brief. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

The list of Key Informants who provided input to this report follows:

[To be added for the final report]

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Patient Safety in Ambulatory Settings

Structured Abstract

Background
Even though the majority of medical care occurs in ambulatory settings, the patient safety movement originated in, and has been mainly focused on, adverse events among hospitalized patients. However, it is increasingly clear that the ambulatory setting is critically important. Ambulatory care differs substantially from inpatient care in ways that affect patient safety interventions. To better understand the scope of ambulatory care safety issues and the types of evaluations that have been reported for ambulatory patient safety practice we have been tasked by AHRQ to provide an overview of key issues relating to the interventions.

Purpose
This technical brief had the following guiding questions:

What are the evidence-based hospital patient safety practices that may be applicable to the ambulatory care setting? What are the ambulatory care patient safety practices that have been studied in the literature? Which ones have not been broadly implemented or studied beyond a single ambulatory care center?

What tools, settings, and other factors (such as implementation of Patient-Centered Medical Home and team-based care) may influence the implementation and spread of ambulatory care patient safety practices?

Methods
We integrated insights from discussions with 8 Key Informants (KIs) with a literature scan.

Findings
Key Informants identified medication safety, diagnosis, transitions, referrals, and testing as important ambulatory care safety topics, and strategies that addressed communications, health IT, teams, patient engagement, organizational approaches, and safety culture as the most important strategies. A literature search of 28 safety topics/strategies found a moderate amount of published intervention evaluations for e-prescribing, medication safety, pharmacist-based interventions, and transitions from hospital to ambulatory care. Published evaluations of interventions for other targets/strategies were few. These results will assist AHRQ in developing a research agenda in ambulatory patient safety.

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Background

Introduction

The Institute of Medicine defines patient safety as "freedom from accidental injury" when engaging in health care. The goal of the patient safety movement is to prevent adverse events in health care. We employ the standard definition of adverse events, as previously adapted for outpatient care: harm to patients arising from medical management, or patient self-management, rather than the natural history of disease.[1-4]

Even though most of medical care occurs in ambulatory settings, the patient safety movement originated in, and has been mainly focused on, adverse events among hospitalized patients. However, it is increasingly clear that the ambulatory setting is critically important; the Institute of Medicine recently opined that adverse events may be more common in ambulatory settings compared to acute care settings.

Ambulatory care differs substantially from inpatient care in ways that affect patient safety interventions. First, ambulatory settings have traditionally lacked electronic health records and other technological tools that can be harnessed for safety. Paper records constitute an impediment to timely safety data management and reporting. Today, the HITECH Act, through which $30 billion of federal incentive payments were distributed to physicians and hospitals to promote digital adoption, has led to increased adoption of Health Information Technology (HIT)[5] in outpatient settings. This makes it more feasible to employ technology-based safety interventions. However, ambulatory care remains fragmented, with the vast majority of care delivered in small practices which routinely interface with providers using different electronic platforms.

Next, the traditional visit-based model of outpatient care, in which patients have limited time with ambulatory providers on a periodic basis, creates potential safety gaps while patients are self-managing, especially for chronic conditions.[6] Finally, the role of the patient is very different in ambulatory care settings than in the hospital.[7] In acute-care settings, patients are under close observation and often passively receive care. In ambulatory settings, patients must decide when to seek medical care, interact with outpatient health systems, and perform their daily health-related tasks. For those with multiple chronic diseases, this includes following a disease-specific medication, diet, and exercise regimen. Some also adjust their medication based on their measurements, such as using glucose monitoring to adjust insulin dosing. When patients have difficulty with these self-management activities, they are at risk for adverse events.

Moreover, human error in the hospital typically refers to errors committed by members of the health care team in a professional setting. When we consider error in outpatient settings, we include possibility of patient errors. The distinction between patient error and patient blame is critical. Errors in self-management can occur because providers or health systems do not provide patients or caregivers with the knowledge or skills that patients need to safely self-manage their health conditions. Patients themselves acknowledge that they can err in self-administering medications or interpreting symptoms.[8] Thus, patient safety issues encompass both the systems issues commonly studied in inpatient settings as well as broader, patient-centered concerns of communication and shared decision-making.

Objective of This Technical Brief

The Agency for Healthcare Research and Quality (AHRQ) has launched a multi-year initiative in Fiscal Year 2015 to expand the scientific evidence, strategies, and tools that are available for improving patient safety in all health care settings so that people can expect safe care whenever and wherever they receive it. AHRQ has focused on two health care settings--ambulatory care and long term care facilities.

To better understand the scope of ambulatory care safety issues and the types of interventions that have been reported for ambulatory patient safety practice we have been tasked by AHRQ to provide an overview of key issues relating to improve patient safety. We combined information we obtained from published literature, gray literature, and Key Informant discussions in order to examine what hospital-based patient safety practices (PSPs) are applicable to ambulatory care, what additional ambulatory care patient safety practices exist, what evaluations have been done of patient safety practices in the ambulatory care setting, what is the amount of, and quality of, the evaluations of patient safety practices in ambulatory care, and what is the evidence about spread and adoption of these practices. We also identified gaps in the current evidence base. Performing a systematic review of the effectiveness of ambulatory patient safety practice interventions is not an objective of this technical brief.

Guiding Questions

The questions below guided the data collection for this technical brief. Question 1 seeks to identify ambulatory care patient safety practices that have been studied and how widely they have been implemented. Question 2 seeks information on organizational settings and other factors that may influence uptake and effectiveness ambulatory care patient safety practices.

Guiding Question 1. What are the evidence-based hospital patient safety practices that may be applicable to the ambulatory care setting? What are the ambulatory care patient safety practices that have been studied in the literature? Which ones have not been broadly implemented or studied beyond a single ambulatory care center?

Guiding Question 2. What tools, settings, and other factors (such as implementation of Patient-Centered Medical Home and team-based care) may influence the implementation and spread of ambulatory care patient safety practices?

Methods

Overview

This technical brief integrates insights from discussions with Key Informants (KIs) with information extracted from the published literature and grey literature. Both Key Informant discussions and literature scan were used to respond to guiding questions 1 and 2. A protocol for the conduct of this work was developed and filed with the Agency for Healthcare Research and Quality (http://effectivehealthcare.ahrq.gov/ehc/products/622/2104/ambulatory-safety-protocol-150724.pdf).

Key Informant Discussions

We identified eight Key Informants from major stakeholder groups such as developers of patient safety practices, policy makers, persons overseeing health plan or organization safety, and including a patient advocate.

In order to help answer guiding question 1, before conducting the interviews the project team evaluated the 41 patient safety practices that were included in the Making Health Care Safer (MHCS) II report[9] and classifying them into one of three categories:

- PSPs with a strong analogy to ambulatory care safety
- PSPs not relevant to ambulatory care
- PSPs with a "partial analogy" to ambulatory care

We also asked the project team and the Task Order Officer for input on any other practices that were not covered in MHCS II. This resulted in a list of 55 topics for which we would seek input from our Key Informants using an online questionnaire.

After the completion of the online questionnaire, we then scheduled teleconferences with our Key Informants. We sent the Key Informants the guiding questions, the protocol, and the list of included/excluded safety practices, and the following list of questions:

1. Are there important PSPs or targets left off the list of includes (in "PSP Survey Results")? Things on the list you would recommend dropping?
2. Do you have any information on organizational models of care that promote patient safety?
3. If you were in charge of the government agency responsible for funding research on patient safety, what is the most important, or the most 3 important, topics for which you would want to see proposals?
4. What are the big categories of patient safety problems, in terms of importance? For some or all of these, we'll ask you to flesh them out a bit in terms of the types of problems and the types of interventions that you think have promise.
5. When you think about patient safety in outpatient settings, what keeps you up at night?

The teleconferences were moderated by the lead investigator and included other members of the project team and, when available, the Task Order Officer (TOO). The discussion was informal while still asking for specific answers to each of the questions. These Key Informant teleconferences were transcribed and assessed for common themes. This was done initially by

one team member, with subsequent input from remaining team members. The summaries of these teleconferences can be found in Appendix B.

Search Strategy

We conducted searches in Medline (PubMed) from 2000 to August 11, 2015. In addition, we searched for gray literature from AHRQ Patient Safety Network (PSNet), the AHRQ Innovations exchange, Institute of Medicine (IOM), the Joint Commission website, the Institute for Safe Medication Practices, Patient Safety Quality Healthcare, and the Pennsylvania Patient Safety Authority Site (PA-PSRS). A separate search was conducted for each of the included patient safety practices. The full search methodology by topic can be found in Appendix A.

Eligibility Criteria

Titles and abstracts were screened by one reviewer to identify studies meeting the following criteria:

1. Hypothesis-testing evaluation of a patient safety intervention
2. In ambulatory care
3. Targeted at safety
4. Reports a safety outcome
5. In a high income country, since the types of safety problems and patient/provider characteristics are probably context-specific.

Articles could have had more than one reason for exclusion, but only one was coded, and a hierarchy for exclusion reasons was not applied. Rather, the first obvious exclusion reason was chosen. Also, studies might appear in one particular PSP search but might be applicable for a different topic, for example a study might appear in a search about "monitoring" but consist of a pharmacist-led intervention to improve medication safety. On full text screening, studies meeting inclusion criteria were coded according to the actual PSP evaluated, and not the search from which it was identified.

When operationalizing these criteria, some of the decisions that needed to be made are as follows.

1. Hypothesis-testing studies included statistical testing of outcomes between two or more comparison groups. Studies reporting only descriptive results of implementation of an intervention were not included (for example, we did not include studies of the implementation of an intervention, such as medication reconciliation, that reported the proportions of patients who had certain kinds of reconciliations performed). Systematic reviews were identified by their use of that word in their title or by following the basic methods of systematic reviews (such as presenting the search strategy, the flow of titles and abstracts leading to articles meeting the eligibility criteria, and the inclusion of evidence tables).

2. Ambulatory care included office-based care only. Studies set in the Emergency Department were considered to be closer to hospital-based care than ambulatory care and

were, in general, not included. Studies set in hemodialysis centers were not included, while studies set in free-standing chemotherapy centers were included. Studies of surgical procedures requiring an operating room were not included, even though the care was delivered in an ambulatory surgery center. Studies of labor and delivery were excluded.

3. Safety outcomes were, in general, defined similar to how they are defined for hospital-based patient safety: they had to be a result of the care given, and not a part of the natural history of disease. Medication adherence was considered a quality outcome and not a safety outcome. Hospital readmission was considered a safety outcome.

4. Interventions whose main target was to increase a process were excluded, unless that process was linked to an outcome. For example, interventions aimed at increasing the use of medication reconciliation were excluded unless there was also an assessment of potential or actual adverse drug reactions.

5. Interventions whose aim was to increase constructs such as teamwork, safety culture, leadership, etc. were excluded unless they also reported a safety outcome.

6. Simulation studies that used students as study subjects were excluded.

7. Studies to improve care of a disease were in general excluded unless safety was the primary outcome. For example, the numerous studies of interventions to improve care of patients with diabetes, which in general use a measure of glucose control like HgbA1c as their principal outcome, were excluded even if they reported differences in hypoglycemic events.

8. Studies of different agents and different delivery models for anticoagulation were considered to be primarily quality and not safety and were excluded.

9. Many interventions could fall into more than one category. For example, studies of interventions to improve hospital-to-community transitions often used pharmacists and their primary goal was medication safety. We classified each study in only one category. Studies of transitions in care were all classified as transitions. Studies not about transitions where pharmacists were the only or principal intervention component were classified as pharmacist's role. Similarly, studies of e-prescribing usually have medication safety as their goal. We classified studies as e-prescribing if that term was used in the article or if it was described as CPOE in the outpatient/ambulatory setting. Such studies could include, and often did include, decision support. Studies of decision support for laboratory test monitoring were classified as medication safety.

Because some searches retrieved very large numbers of titles, for these searches we reduced the number of titles to be screened by requiring the word "safety" be included, or the study was published out of the leading general interest medical journals or the leading specialty journals for patient safety. We validated this "reduced titles" strategy by comparing titles selected thus to a 10% sample of the full search titles for the first three such topics, on patient engagement, the workforce, and infection control. No studies meeting inclusion criteria were

missed using the "reduced titles" search and we thus concluded this was an acceptable method for estimating the amount of available studies in those topics.

Abstracts potentially meeting these inclusion criteria had full text articles retrieved and assessed by one reviewer. Studies included at this stage were then classified by:

- The patient safety target or practice
- The study design, with the categories Systematic Review, Randomized Controlled Trial, or Other Hypothesis-Testing Study.
- Whether the intervention was tested in a single setting (single office-based setting or plan) or whether it was tested in multiple settings. Studies tested in multiple sites within a health care delivery system that shares characteristics across sites, such as Kaiser or the Veteran Affairs, were considered to be equivalent to "single site" implementations.
- Data from the title and abstract and full text screening were tabulated for ease of comparison.

Findings

Overview

The results of the questionnaire matrix and key informant interviews identified 28 patient safety practices or targets, not mutually exclusive, that had relevance to the ambulatory care setting. Separate searches on each in PubMed yielded more than 20,000 titles. Titles, abstracts, and full text screening yielded 145 potentially relevant studies, which were mostly concentrated in a few PSPs. The Key Informant interviews were analyzed for themes, which were summarized across two domains. We have included the table of themes in Appendix C.

Results of the Questionnaire matrix

After receiving input from our project team, an online questionnaire was sent out to our Key Informants to evaluate which patient safety practices should or shouldn't be included in our list of practices to focus on. In addition, we asked the Key Informants for additional practices that were not on the list. Completion of the questionnaire by all eight Key Informants and the project team's input yielded a list of 28 patient safety practices relevant to ambulatory care settings and 27 excluded practices not relevant to patient safety practices in ambulatory care settings (see Table 1).

Table 1. Patient safety practices evaluated

PSPs included
Use of Simulation Exercises in Patient Safety Efforts
Obtaining Informed Consent From Patients
Team-Training in Health Care
Computerized Provider Order Entry With Clinical Decision Support Systems
Workforce issues (job satisfaction, environment, etc)
Transitions other than hospital to ambulatory care – care coordination
Self-management of high risk medications (insulin, anticoagulation, immunomodulatory therapy)
Chronic Opioid use
Tracking test results so things don't slip through the cracks (all diagnostic and prevention testing and screening)
Monitoring for medication safety beyond the initial decision to prescribe
Referring risks--Was the best referral made? Was information communicated well enough? Who is responsible for what? (Responsibility and accountability)
Issues of multimorbidity/frail elders beyond polypharmacy
Phone triage—Who staffs it? What support tools are used?
Mental health diagnosis/treatments in the context of integrated health (co-located primary care and mental health) – mental/psychological health across all ambulatory settings
Health Literacy
Infection control and prevention of office-based acquired infections (hand hygiene is on top but there are other issues)
The Joint Commission's "Do Not Use" List
Interventions To Improve Hand Hygiene Compliance
Ensuring Documentation of Patients' Preferences for Life-Sustaining Treatment
Human Factors and Ergonomics
Promoting Engagement by Patients and Families To Reduce Adverse Events/Responsibilities in safety practices
Promoting Culture of Safety
Patient Safety Practices Targeted at Diagnostic Errors
Interventions to Improve Care Transitions at Hospital Discharge
Clinical Pharmacist's Role in Preventing Adverse Drug Events
Medication Reconciliation Supported by Clinical Pharmacists
Monitoring Patient Safety Problems

Preventing Patient Death or Serious Injury Associated With Radiation Exposure From Fluoroscopy and Computed Tomography
PSPs excluded
Identifying Patients at Risk for Suicide
Prevention of Venous Thromboembolism
Issues around Telehealth
Reducing Unnecessary Urinary Catheter Use and Other Strategies To Prevent Catheter-Associated Urinary Tract Infections
Prevention of Central Line-Associated Bloodstream Infections
Interventions To Allow the Reuse of Single-Use Devices
Use of Real-Time Ultrasound Guidance During Central Line Insertion
Interventions To Prevent Contrast-Induced Acute Kidney Injury
Administration of blood products
High-Alert Drugs: Patient Safety Practices for Intravenous Anticoagulants
Barrier Precautions, Patient Isolation, and Routine Surveillance for prevention of Healthcare-Associated Infections
Ventilator-Associated Pneumonia
Preoperative and Anesthesia Checklists
Use of Report Cards and Outcome Measurements To Improve Safety of Surgical Care: American College of Surgeons National Surgical Quality Improvement Program
Prevention of Surgical Items Being Left Inside Patient
Operating Room Integration and Display Systems
Use of Beta Blockers To Prevent Perioperative Cardiac Events
Preventing In-Facility Falls
Preventing In-Facility Delirium
Preventing In-Facility Pressure Ulcers
Inpatient Intensive Glucose Control Strategies To Reduce Death and Infection
Rapid Response Systems
Strategies To Prevent Stress-Related Gastrointestinal Bleeding (Stress Ulcer Prophylaxis)
Effect of Nurse-to-Patient Staffing Ratios on Patient Morbidity and Mortality
Tubing Misconnections
Limiting Individual Provider's Hours of Service (this is in the context of physicians-in-training)
Smart Pumps and Other Protocols for Infusion Pumps

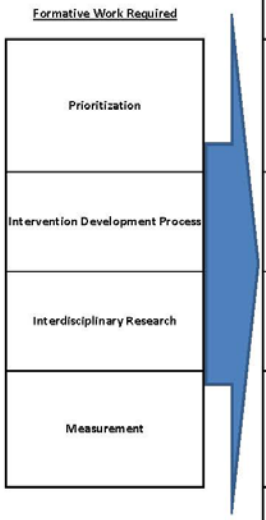
Table Note: PSPs=Patient Safety Practices

This list was reviewed during our Key Informant interviews, and no substantive changes were made. The project team and Key Informants recognized that many of these included PSPs overlapped, and some published PSPs may fall into more than one category.

Key Informant Interviews

The Key Informants provided wide ranging views on numerous topics related to ambulatory patient safety, which we have organized into the following areas: the need for more fundamental formative work on the implementation of interventions and better measures of safety, specific ambulatory patient safety practices and concerns (which we refer to as safety issues), and cross-cutting patient safety strategies. We have summarized the interviews in Figure 1 as a matrix encompassing ambulatory care safety (a row for each of five safety issues) and strategies typically considered to address these vulnerabilities (a column for each of six cross-cutting strategies).

Figure 1. Matrix Key Informant Themes



Safety Issues	General comments → ↓	Communication Problem Cross-cutting vulnerability Intervention PCMH has better communication built in which may promote safety	Health IT Problem - Alert fatigue - Work arounds - Poor EHR usability → burnout Intervention - Potential to be transformative - Health information exchanges	Teams Problem NPs underutilized Intervention - Mix of skills promotes safety - PCMH has teams and this may promote safety	Patient-engagement Intervention - Shared decision making - Health literacy	Organizational Approaches Problem Lack of infrastructure and skills to deal with safety issues Intervention - Care coordination - Improved information flow PCMH	Measurement Problem Lack of validated measures Intervention Need multiple ways to measure
Prescribing and Medication Errors	Definition Prescribing, dispensing, interactions, monitoring Non-adherence as safety problem Intervention - National action plan - Anti-biotic stewardship - Allergy documentation	Intervention - Clear, consistent medication instructions - Changes made to Rx in writing for consistency from electronic order to pharmacy to bottle	Intervention - Decision support - Changes made to Rx in writing for consistency from electronic order to pharmacy to bottle	Intervention Pharmacist on team (PINCER trial, now in practice in UK)	Problem Lack of patient engagement	Problem Current systems don't support ongoing monitoring Intervention - Prescribing checklist - Educate patients about self-management of meds	
Diagnostic Errors	Knowledge Gap Lack of epidemiologic data	Intervention Three-way or more consultation amongst specialists	Intervention Decision support		Problem Lack of information and tools for patients to improve diagnosis	Problem Little tracking and reporting, awareness Intervention real time investigative procedures	
Transitions	Definition - In/out of hospital care - In/ out of social services - Multi-morbidity - Pediatrics to adults	Intervention Need for synchronous communication when patient transitions	Intervention Interoperability needed	Intervention Make sure information moves with patient during transitions	Problem Lack of effective patient education Intervention Self-care training		
Referrals	Problem Challenge to reach correct person in timely fashion Intervention Follow-up/continuity					Problem - Perverse financial incentives - Unclear referral reasons	
Culture	Problem - Fear of speaking up about perceived safety concerns - Uncertainly about safety event reporting					Problem Complacency issues	
Testing	Problem - Ordering the wrong tests - Poor interpretation of tests Intervention Standard procedures					Problem Lack of systemization for the testing process in current practice	

Figure notes: IT=Information Technology; PCMH=Patient-Centered Medical Homes; gray boxes represents intersections of issues and strategies that KIs did not discuss.

Formative Work

Key Informants emphasized the importance of additional formative work in ambulatory safety in addition to testing and implementation of interventions. This formative work would inform the entire range of safety issues discussed. Several of the Key Informants recommended that AHRQ convene a consensus process of some kind to prioritize ambulatory safety issues would lend consistency to local efforts. Several asserted that inquiry into intervention development would increase the uptake and effectiveness of patient safety promotion activities. During each Key Informant call, the importance of interdisciplinary perspectives, including medicine, nursing, human factors, and the social sciences, was mentioned several times. Lack of validated measures remains a pervasive problem. Because ambulatory care is decentralized, Key Informants recommended use of multiple measures which can be triangulated in order to establish the burden of outpatient safety problems. One emphasized the importance of developing consensus for measures in order to bring consistency and comparability across studies. The field could also benefit from consistent definitions of safety topics.

Safety Issues

The Key Informants reflected on the wide range of safety practices included. Multiple Key Informants felt there was a distinction between PSPs that reflected concrete patient safety issues, such as hand hygiene, and PSPs that represented cross-cutting patient safety strategies, such as "promoting a culture of safety." One key informant urged us to consider patient safety strategies separately from specific patient safety issues, because different sets of interventions are needed to address cross-cutting strategies than to address specific patient safety topics. Another recommended considering the strategy and the topic jointly during the intervention design phase. Figure 1 provides some examples of such joint consideration (e.g., decision support as an intervention representing an HIT strategy, and directed at two safety topics).

Across all the discussions, Key Informants mentioned 5 concrete safety issues: medication safety, diagnosis, transitions among providers in ambulatory settings, referrals from one provider to another, and management of test results. There was agreement that each of these issues is complex, multi-faceted, and important for patient safety. They began with general comments about each issue. Briefly, medication safety was defined broadly to include any deviation from optimal medication use, including errors in prescribing, dispensing, and monitoring, failure to note medication interactions or appropriately discontinue medications. Some aspects of medication non-adherence were also seen as safety problems. Multiple KIs gave the same example: a non-adherent patient whose physician adds more antihypertensive agents to his regimen, causing the patient to become over-medicated when he adheres. Delayed or missed diagnosis was felt to be a significant problem needing additional formative and descriptive work on a large scale. Participants noted that ambulatory care is rife with transitions, and recommended looking at transitions broadly, as interactions between all parties involved in patients' health. The referral process also is vulnerable to safety gaps; patients and subspecialty providers often do not know the reason for a visit, and the primary care provider may not receive timely information and feedback. Diagnostic testing exhibits widespread problems in notification and tracking of test results, and patients are variably aware of clinically relevant results.

Strategies

KIs also discussed strategies that can be used to improve safety across multiple specific topics. Patient engagement is an example of a safety strategy that could address both diagnostic and medication safety. Six cross-cutting safety strategies emerged from the KI discussions: communication, health information technology (HIT), teams, patient and family engagement, organizational approaches, and safety culture. These six areas can be both facilitators of ambulatory safety and, if lacking or sub-optimal, barriers to safety. KIs provided both general input about each area and topic-specific input, which we discuss below.

Communication is clearly critical to ambulatory safety. KIs view current communication processes as vulnerable to safety problems. Some specific vulnerabilities included the lack of implementation of clear medication instructions, despite the availability of evidence-based medication instructions that enhance comprehension. Similarly, lack of group communication among multiple providers was viewed as a barrier to timely and accurate diagnosis. Experts reported an unmet need for synchronous communication at times of transition in outpatient settings. One key informant suggested that the communication practices embedded in the Patient-Centered Medical Home (PCMH) have the potential to enhance patient safety.

Health information technology was cited as both a strategy to improve safety and a barrier to safety. KIs considered poor usability of current electronic health records (EHRs) to be a safety vulnerability and a source of clinician burnout. They cited the increasing reports of alert fatigue, in which the proliferation of meaningless alerts leads to clinicians ignoring automated alerts. There was also concern about the quality of communication in visits when the physician or provider is focused on the electronic health record. However, there was agreement among KIs that health information technology has potential to improve safety in outpatient settings broadly and for specific safety issues like transitions in care and diagnosis. Technology also has the potential to engage patients, especially between visits.

How work roles within teams are constructed, workflow managed, and teamwork monitored all have potential consequences for patient safety. For ambulatory care, the KIs envisioned increasing the role of non-physician providers in order to foster safety. Including pharmacists on ambulatory teams was specifically mentioned, as was employing a team approach to transitions.

KIs consistently highlighted the importance of patient engagement since ambulatory encounters are rare and brief compared to daily self-management. It is critical that patient engagement encompasses populations with limited health literacy, limited English proficiency, and other social vulnerabilities. Making the health system easier for patients to navigate was felt to confer safety benefit.

KIs expressed concern about the notable lack of existing organizational approaches in current practice that support ambulatory safety. They also expressed concern about "complacency" about errors in outpatient practice and believed that strengthening reporting and feedback mechanisms would help. KIs felt that the patient-centered medical home (PCMH) approach had promise, and recommended further study of how PCMH transformation affects adverse event incidence.

Measurement remains a challenge for outpatient safety. Currently, we do not have effective measurement strategies. KIs believed that multiple modes of measurement including EHR-derived measures, patient and clinician reports, and record review, would need to be used in combination to effectively detect and measure the spectrum of ambulatory safety gaps.

Finally, an over-arching theme that emerged from the discussions was the current rapid transformation of the ambulatory environment, and the need to take this rapidly changing context into account when examining safety hazards and interventions to improve outpatient safety. Much of the current literature is situated in traditional outpatient care models which may not apply going forward. Thus, there is an urgent need for rapid-cycle evaluation of new care delivery models with respect to safety.

Literature scan

Figure 2 presents the results of the screening of the titles, abstracts, and full text articles. The 28 searches of PubMed yielded a total of 21,927 titles with an additional 61 titles coming from gray literature. Some titles appeared in more than one search, and as we did not de-duplicate these 28 searches the total number of unique titles is somewhat less. From these titles, one reviewer screened the titles, abstract, and full text articles. The majority of studies excluded at this stage were because they were not hypothesis-testing studies of patient safety interventions, or not about patient safety, or not based in ambulatory care (see Figure 2).

Of the 3,039 abstracts selected for further evaluation, 319 articles were retrieved and reviewed at the time of this draft report; the remaining 62 articles remain to be retrieved. One hundred and seventy-nine were rejected on further review, most because they were not hypothesis-testing studies of patient safety practices. One hundred and forty studies met our eligibility criteria.

Figure 2. Overview of screening

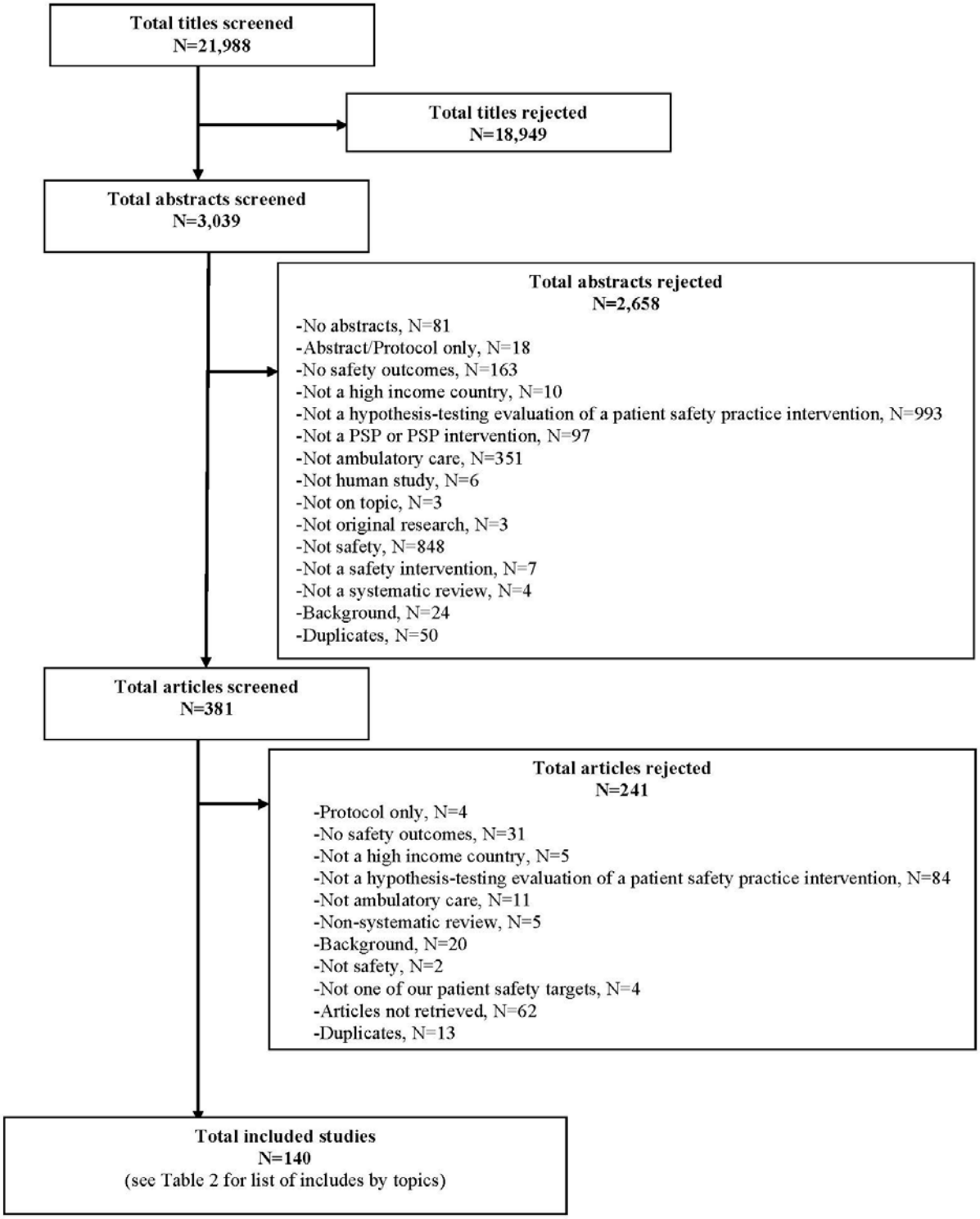


Figure notes: PSP(s)=Patient Safety Practice(s)

Of the studies meeting eligibility criteria, the PSPs with the greatest number of studies were e-prescribing, medication safety, pharmacist-led interventions, and transitions of care (see Table 2). These PSPs also all already have systematic reviews of their effectiveness (60 percent published within the past two years), although not all the reviews are exclusively focused on ambulatory care-based versions of these interventions. Studies meeting eligibility criteria for the other PSPs or safety targets were few. Those PSPs that have systematic reviews have been implemented in more than one setting, although frequently the exact nature of the PSP differs from study to study (for example, studies of pharmacist-led interventions vary in exactly what the pharmacist does and when). PSPs for which published studies are few have, in general, only been assessed in a single setting. The list of included studies by topic can be found in Appendix D.

We did not identify any studies, focusing on Guiding Question #2, concerning organizational models that promote the uptake and spread of ambulatory patient safety practices.

Table 2. Included studies by topic

	Included studies, N=140				
	Study Design				
Safety Practice	Systematic Review	RCT	Other hypothesis testing study	Practice guideline	**TOTAL**
Diagnostic errors					0
E-prescribing	6	2	20		28
Hand hygiene			2		2
Health literacy			1		1
Human factors		1			1
Infection control			2	1	3
Informed consent			1		1
JCAHO "Do Not Use" list					0
Life-sustaining treatment					0
Medication safety	5	12	16		33
Mental health					0
Monitoring			1		1
Multimorbidity					0
Opioid use			3		3
Patient engagement		4	2		6
Pharmacists' role	2	1	9		12
Radiation exposure			1		1
Referrals					0
Safety culture		1			1
Self-management					0
Simulation			7		7
Team-training			1		1
Telephone triage	3		3		6
Tracking test results		1	2		3
Transitions	7	10	13		30
Workforce					0
TOTALS:	**23**	**32**	**84**	**1**	**140**

notes: PSP(s)=Patient Safety Practice(s)

Summary and Implications

These results shed light on the current state of ambulatory safety evaluation. The combination of input from Key Informants and the literature scan demonstrate that although there is some overlap in the hospital-based and ambulatory safety topics, there are distinct safety issues in the ambulatory environment. The Key Informants identified 28 hospital safety practices most relevant to ambulatory safety. The results of our literature scan showed a few of these PSPs have a moderate evidence base, for example e-prescribing, medication safety, transitions from hospital to the ambulatory setting, and pharmacist-led interventions. However, most PSPs have few or even zero studies evaluating use in ambulatory care. Patient safety culture seems to be an area of challenge for outpatient safety. As an example, KIs described a general acceptance of sub-optimal results reporting and tracking. Reporting systems for errors are under-developed, and it is not clear what feedback results from such systems. It seems the fear of speaking up persists as well. Notably, widely-used safety culture surveys or team training were not discussed during KI calls. Health information technology has been disruptive in ambulatory care, with possible safety advantages and many unintended consequences. Advantages such as widespread information-sharing through health information exchanges were perceived as theoretical rather than actually functioning today. Many Key Informants mentioned struggles with poorly designed, expensive, cumbersome electronic health records as a source of physician burnout, which they see as a safety hazard. Health information technology implementation emerged as a needed area of study, because of the concerns about alert fatigue and "workarounds" that may worsen safety.

Both the literature scan and the key informant interviews indicate significant knowledge and implementation gaps. Other than the medication-related and car transitions practices mentioned above, few of the PSPs have significant evidence in outpatient settings, and fewer still have been widely implemented. The key informant interviews highlighted the lack of large-scale epidemiologic studies and multi-center interventions across all topics. Interviews also emphasized the need for more research on diagnosis, as described in a recent IOM report.[10] We did not identify literature indicating specific organizational models of care to support ambulatory safety, although our Key Informants suggested that patient centered medical home and team-based care models may hold promise.

These results inform a significant future research agenda. First, measurement development efforts are needed directed at each of the safety topics the KIs focused on- medication safety, diagnosis, transitions, referrals, and testing. There should be multiple measures that can serve as outcomes for research, and there should be efforts made to support development of performance measures. Second, research in patient safety needs to incorporate multiple disciplines with multiple methods. KIs felt that more rigor needs to be brought to the science of intervention development before those interventions are evaluated in well-designed hypothesis-testing studies. There should also be further emphasis on implementation studies to understand what promotes implementation, sustainment, and spread of successful ambulatory safety practices. Third, it is clear that there is a need to invest in improving the safety of the diagnostic process. Several Key Informants emphasized the need for collection of primary, descriptive data in order to understand diagnostic accuracy. Fourth, transitions in care has come to mean post-hospital discharge, but the Key Informants uncovered many other unsafe transitions- amongst outpatient

providers, between health care and social services, and managing pediatric to adult transitions for the chronically ill, most of which have not been the subject of a single PSP evaluation. The epidemiology of adverse events in these transitions warrants further study in preparation for developing effective patient, provider, and system-level interventions. Taken together, our results suggest the need for large-scale, prospective descriptive and intervention studies across multiple ambulatory environments in order to establish real-world evidence to support safer care in ambulatory settings.

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Acronyms and Abbreviations

AHRQ	Agency for Healthcare Research and Quality
HIT	Health Information Technology
IOM	Institute of Medicine
KI(s)	Key Informant(s)
PA-PSRS	Pennsylvania Patient Safety Authority Site
PCMH	Patient-Centered Medical Homes
PSP(s)	Patient Safety Practice(s)
RCT	Randomized Controlled Trial
SR	Systematic Review
TOO	Task Order Officer